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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,014	03/26/2004	David G. Wild	CV0330 NP	9570
26079	7590	06/13/2008	EXAMINER	
BRISTOL-MYERS SQUIBB COMPANY			OSTRUPE, CLINTON T	
100 HEADQUARTERS PARK DRIVE				
SKILLMAN, NJ 08558			ART UNIT	PAPER NUMBER
			3771	
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			06/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,014	WILD ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 February 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5,7,8,10,11,14,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5,7,8,10,11,14,19 and 20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/18/04</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. This Office Action is responsive to the amendment filed on 2/15/08. As directed by the amendment, claim 1 has been amended. Claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 are presently pending in this application.

Specification

2. The disclosure is objected to because of the following informalities: the disclosure lacks antecedent basis for the claimed limitation wherein the leg cuff consists of only three "undivided" cells. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5, 7-8, 10-11, 14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barak in view of Calderon et al. (6,589,194) and further in view of Jensen et al., (2004/0111048).

Re claim 1, Barak discloses a compression device for the limb of a mobile patient (fig. 1) comprising: an inflatable sleeve 1 (fig. 2) adapted to surround the limb; a conduit 4 attached to said sleeve for delivering fluid to said sleeve; and a portable, wearable controller 3 (fig. 1) or control unit 68 (col. 6, lines 63-67) attached to said conduit that generates and controls the flow of fluid in the device; wherein the sleeve includes a leg cuff and a foot cuff (fig. 2); the leg cuff comprises only three undivided

(they are not separated by space) cells: a gaiter cell 2 adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2 adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2 adapted to wrap around the lower limb in the region between the mid-calf cell and the knee (best seen in fig. 2), except that it does not explicitly disclose that the sleeve includes consists of a leg cuff and a foot cuff.

However, Barak teaches that “the invention is also intended for use on any body limb such as a foot, a part of a leg” (col. 4, lines 14-15) and “the number of cells in the sleeve can vary, according to the desired treatment” (col. 10, lines 34-35). Moreover, Calderon et al. teaches a similar compression device having a sleeve consisted of a leg cuff 2B-D and a foot cuff 2A (fig. 1); the leg cuff consists of three cells: a gaiter cell 2B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2D adapted to wrap around the lower limb in the region between the mid-calf cell and the knee in the form of a shoe, boot or stocking (col. 3, lines 40-43) for treatment of edema and varicose veins (see abstract) to a lower limb (fig. 1).

Therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to limit the Barak’ device to include only a leg cuff and a foot cuff to treat the lower limb in the form a shoe, boot or stocking, as suggested by Calderon et al., for the purpose of providing treatment of edema and varicose veins locally to a lower limb.

Furthermore, since Barak already teaches that “various changes, **omissions** to the form and detail thereof may be made therein” (col. 10, lines 38-40), therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to eliminate the cell of the thigh, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

Re claims 2-3, 5, 7, Barak discloses the controller comprises a microprocessor control system (control unit 68, col. 6, lines 63-67) and a pump (pump unit 60, col. 6, lines 22-33); wherein at least one pressure sensor 62/63 or pressure monitoring means (col. 6, lines 37-38) is associated with said sleeve ; wherein said sleeve is low profile and discrete (fig. 1); said leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow (best seen in fig. 2).

Re claims 10-11 and 19, Barak discloses that the controller is battery operated (rechargeable battery pack 67, col. 6, lines 26-28); wherein each cell is monitored by a sensor 62/63 (col. 6, lines 37-38); and a method of preventing or treating edema or DVT (col. 2, lines 42-49) comprising applying a compression device of claim 1 to the limb of a mobile patient.

Re claims 8 and 20, Barak discloses the claimed inventions having all the features except for a sock interposed between the sleeve and the limb. Calderon et al. teaches a similar compression device having a sleeve comprising a plurality of cells 2A-

D for treatment of edema and venous disorder (fig. 1). Further more, Calderon also teaches that the inner surface of the sleeve “is preferably smooth to engage the skin or a sock or stocking” (col. 3, lines 63-65), thus suggesting that a sock may be worn by the user and is interposed between the sleeve and the limb. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to further modify the Barak’ device, to include a sock interposed between the sleeve and the limb, as suggested by Calderon et al., for the purpose of preventing skin irritation, skin shear and chaffing at the contact surface between the device and the skin of the limb during use.

Re claim 14, Barak discloses the claimed inventions having all the features except it is silent regarding the cells may be pressurized to the same or different predetermined pressures. However, Barak teaches (fig. 5) a pressure system 50 that has a range of pressure of 50-100 mmHg, and therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to operate the Bark’s pressure system, such that the cells may be pressurized to the same or different predetermined pressures, for the purpose of providing a variety of compression therapy being applied on different body parts of the patient suitable to the patient’s condition.

Response to Arguments

4. Applicant's arguments filed 2/15/2008 have been fully considered but they are not persuasive.

In response to applicant's argument that "Thus, from reading Barak, et al., one of ordinary skill in the art would believe that it is essential to pressurize the thigh in order to obtain benefit from that device", the examiner respectfully disagrees.

There is no evidence disclosed in Barak et al. to teach that the device would not work without the thigh cuff. Furthermore, since Barak already teaches that "the number of cells in the sleeve can vary, according to the desired treatment" (col. 10, lines 34-35) and "various changes, omissions to the form and detail thereof may be made therein" (col. 10, lines 38-40), therefore there appears to be no unobviousness for Barak to apply pressure only to the foot and leg, especially in view of the teaching of Calderon, which clearly teaches a compression device having a sleeve consisted of a leg cuff 2B-D and a foot cuff 2A (fig. 1); the leg cuff comprises only three cells, which are not divided by space: a gaiter cell 2B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2D adapted to wrap around the lower limb in the region between the mid-calf cell and the knee in the form of a shoe, boot or stocking (col. 3, lines 40-43) for treatment of edema and varicose veins (see abstract) to a lower limb (fig. 1).

In response to applicant's arguments against the references individually one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant specifically argues that Barak, et al. does not teach that treatment

only below the knee is effective and that the Barak, et al. device, when used on the leg, has a thigh cuff and a lower leg cuff. Thus, applicant argues that Barak et al. does not suggested that the thigh cuff can be eliminated.

In this case, the only difference between the present invention and Bark's device is that the thigh cuff is present. Calderon is cited to teach a compression device having a sleeve consisted of a leg cuff 2B-D and a foot cuff 2A (fig. 1); the leg cuff is consisted of three cells: a gaiter cell 2B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2D adapted to wrap around the lower limb in the region between the mid-calf cell and the knee in the form of a shoe, boot or stocking (col. 3, lines 40-43) for treatment of edema and varicose veins (see abstract) to a lower limb (fig. 1). Therefore there appears to be no unobviousness for Barak to eliminate the thigh cuff to apply pressure only to the foot and leg, especially in view of the teaching of Calderon.

In response to applicant's argument that "Barak, et al. does not suggest that it is possible to eliminate the thigh cuff and it certainly does not teach that doing so would make an effective device", the applicant's attention is directed Bark's teaching in col. 10, lines 38-40, which clearly stated that "various changes, emissions to the form and detail thereof may be made therein" and thus omissions of the thigh cuff is possible, especially in view of the teaching of Calderon as discussed above.

Applicant has not provided evidence that the Bark's device would not work effectively if the thigh cuff is eliminated. Moreover, it has been held that omission of an

element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the cells, when inflated, presents a smooth surface to the limb of the patient and apply an even compression to the limb) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding applicants argument that the three cells of Barak are not undivided, the examiner respectfully disagrees. The cells of Barak are undivided, as they are not separated by space.

Regarding applicant's argument that there is no incentive to make eliminate the thigh cuff of Barak and the foot pump in Calderon, to arrive at the claimed invention. The examiner respectfully disagrees.

First, when a physician is treating a patient, they treat the part of the body in need of said treatment. Thus, if a physician was to treat a lower leg, it would be obvious to modify a leg treatment device to treat only the body part needing treatment. Since Barak discloses that "The control unit, which can be software based, controls the operation of the compressor and solenoid valves. The control unit can be programmed to achieve any desired inflating and deflating sequence and timing including delay

intervals, in accordance with clinical application.” Thus, a physician treating the lower leg could program the control unit to deflate and indefinitely delay inflating of the thigh portion of the device.

Regarding applicant's argument regarding the necessity of eliminating the foot pump of Calderon to arrive at applicants invention, Barak discloses the pump and Calderon was used to show the obviousness of forming a device with a leg and foot cuff. Thus, the combined references teach the device as claimed and the incentive for modifying the device is to treat the portion of the leg in need of treatment as determined by one having ordinary skill in the art.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jensen et al., (2004/0111048); Taheri (4,941,458); Taheri (4,624,244) which are all drawn to leg compression devices.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771